JUN 1 0 2004

K040926

PREMARKET NOTIFICATION 510(K) SUMMARY

1. **Submitted By:** Hudson Diagnostic Imaging LLC
   610 Boulevard
   Elmwood Park, NJ 07407

2. **Contact Person:** Dr. Martin E. Wendelken

3. **Name Of Device/s:**

   a. Trade Names: Hudson 8000 Ultrasound Scanner*
   Hudson 9000 Ultrasound Scanner**

   b. Common Name: Ultrasound Scanner

   c. Classification Name: Ultrasonic pulsed echo imaging system
   FR No. 892.1560 Product Code: 90-IYN

4. **Legally Marketed Device for which we are claiming substantial equivalence:**

Scanner Trade Names: Mycolor 202 (Pico) Ultrasound Imaging System*
Manufactured and Distributed by:
Medison America Inc.
11075 Knott Avenue
Cypress, CA 90630
Scanner 510(k) Number: K031552

Scanner Trade Names: Aloka SSD-900 Ultrasound Imaging System**
Manufactured and Distributed By::
Aloka Co. Ltd.
10 Fairfield Boulevard
Wallingford, CT 06492

Scanner 510(k) Numbers: K983879

Scanner Trade Names:Hudson 2020, 2040, and 2060 Ultrasound Imaging Systems
Distributed by :
Hudson Diagnostic Imaging LLC
610 Boulevard
Elmwood Park, NJ 07407
Scanner 510(k) Number: K011284

5. **Description of the Device:**

The Hudson 8000 & 9000 Imaging Systems are diagnostic ultrasound scanners which incorporates a proprietary method of imaging wounds both cavernous and non-cavernous types. The ultrasound scanners use linear array transducers (5—10 Mhz) . The scanners are capable of imaging wounds including pressure ulcers which may invade and penetrate tissues as much as 6 cm in some areas of the body.

6. **Intended Use of the Device:**

High resolution ultrasound imaging of wounds

7. **Summary of Technological Characteristics compared to Predicate Device:**

The technological characteristic the predicate devices are equivalent. The incorporation of the Wendelken / Pope method of imaging wounds using diagnostic ultrasound along with predicate and equivalent ultrasound contact media provides for the imaging of wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Dr. Martin E. Wendelken
Official Correspondent
Hudson Diagnostic Imaging L.L.C.
610 Boulevard
ELMWOOD PARK NJ 07407

Re: K040926
Trade Name: Hudson 8000 and 9000 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: April 7, 2004
Received: April 26, 2004

Dear Dr. Wendelken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the Hudson 9000 Ultrasound System with UST-5524—7.5 40mm Linear Array Transducer and the following transducers intended for use with the Hudson 8000 Ultrasound System as described in your premarket notification:

HL 5-9ED 5-9 MHz Linear Array
C2-4ES Curved Linear Array
C3-7ED Curved Linear Array
HC2-5ED Curved Linear Array
EC4-9/10ED Endocavity Curved Linear Array
EC4-9ES Endocavity Curved Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

David A. Lazarus

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Hudson 8000 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			Note 2	Note;3,4,6
Abdominal		P	P	P		P			Note 2	Note3,4,6
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P			Note 2	Note3,4,5
Small Organ (specify)		P	P	P		P			Note 2	Note;3,4,5,6
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P			Note 2	Note 7
Transesophageal										
Transrectal		P	P	P		P			Note 2	Note 3,6
Transvaginal		P	P	P		P			Note 2	Note 3,6
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P			Note 2	Note 3,5,6
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P			Note 2	Note3,5,6
Musculo-skeletal Superficial		P	P	P		P			Note 2	Note 3,5,6
Other (specify) Wounds		N		N		N			N-Note 1	Note2,3,6

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Note 1: In conjunction with Wendelken / Pope scanning method and contact media.

Note 2: PWD/Color Doppler, PWD/Power Doppler; CWD/Color Doppler; CWD/ Power Doppler

Note 3: Includes Imaging for guidance of Biospy- Note 4: Tissue Harmonic Imaging

Note 5: Example: Thyroid, ParaThyroid, Breast, Scrotum, & Penis in adult, pediatric and neonatal patients

Note 6: 3D Imaging Note 7: Color M mode NoteHudson 8000 Scanner is a relabeled Medison Pico Scanner

See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040926

Hudson HL 5-9ED—5-9 Mhz Linear Array Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P			P- Notes:	1,2,3,4
Small Organ (specify)		P	P	P		P			P- Notes:	A,1,2,3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P			P- Notes:	1,2, 3
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P			P- Notes:	1,2, 3
Musculo-skeletal Superficial		P	P	P		P			P- Notes:	1,2, 3
Other (specify) Wounds		N		N		N			N-Note 1	Note:2,3

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: In conjunction with Wendelken / Pope scanning method and contact media.

Note A: Thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 1: PWD/Color Doppler, PWD/Power Doppler Note 2: 3D imaging

Note 3: CWD/ Color Doppler, CWD / Power Doppler Note 4: Tissue Harmonic imaging

Note 5: The Hudson HL 5-9ED probe is a relabeled Medison HL 5-9 ED probe—See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson C2-4ES– Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult		P	P	P		P			Note: 1	Note: 2
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler

Note 2: Color M Mode

Note 3: The Hudson C2-4 ES probe is a relabeled Medison C2-4 ES probe See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson C3-7ED– Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			Note: 1	Note:2,3,4
Abdominal		P	P	P		P			Note: 1	Note:2,3,4
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P			Note: 1	Note:2,3,4
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler;

Note 2: Includes imaging for guidance of biospy Note 3: Tissue Harmonic Imaging Note 4: 3D Imaging

Note 4: The Hudson C3-7 ED probe is a relabeled Medison C3-7 ED probe—See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepsom

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson C3-7ED– Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			Note: 1	Note:2,3,4
Abdominal		P	P	P		P			Note: 1	Note:2,3,4
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P			Note: 1	Note:2,3,4
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler;

Note 2: Includes imaging for guidance of biospy Note 3: Tissue Harmonic Imaging Note 4: 3D Imaging

Note 4: The Hudson C3-7 ED probe is a relabeled Medison C3-7 ED probe—See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lejeune

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson HC2-5ED – Curved Linear Array Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			Note: 1	Note:2,3,4
Abdominal		P	P	P		P			Note: 1	Note:2,3,4
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P			Note: 1	Note:2,3,4
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler;
Note 2: Includes imaging for guidance of biospy Note 3: Tissue Harmonic Imaging Note 4: 3D Imaging
Note 5: The Hudson HC2-5 ED probe is a relabeled Medison HC2 2-5 ED probe See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrow

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

Prescription Use (Per 21 CFR 801.109) 510(k) Number K040926

Hudson EC4-9/10ED– Endocavity Curved Linear Array

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P			Note: 1	Note:2,,4
Transvaginal		P	P	P		P			Note: 1	Note:2,3,4
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler

Note 2: Includes imaging for guidance of biospy

Note 3: Includes infertility monitoring of follicle development Note 4: 3D Imaging

Note 5: The Hudson EC 4-9/10ED probe is a relabeled Medison EC 4-9/10 ED probe - See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson EC4-9ES– Endocavity Curved Linear Array

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P			Note: 1	Note:2,,4
Transvaginal		P	P	P		P			Note: 1	Note:2,3,4
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1:PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler

Note 2: Includes imaging for guidance of biospy

Note 3: Includes infertility monitoring of follicle development Note 4: 3D Imaging

Note 5: The Hudson EC4-9ES probe is a relabeled Medison EC4-9 ES probe—See K031552

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson 9000 Ultrasound System

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		P	P						B/M	
Fetal		P	P						B/M	
Abdominal		P	P						B/M	
Intraoperative		P	P						B/M	
Intraoperative Neurological		P	P						B/M	
Pediatric		P	P						B/M	
Small Organ (specify)		P	P						B/M	Note 2
Neonatal Cephalic		P	P						B/M	
Adult Cephalic		P	P						B/M	
Cardiac Pediatric										
Transesophageal		P	P						B/M	
Transrectal		P	P						B/M	
Transvaginal										
Transurethral										
Intravascular		P	P						B/M	
Peripheral Vascular		P	P						B/M	
Laparoscopic		P	P						B/M	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial Wounds										
Other (specify)		N	N						B/M	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: In conjunction with Wendelken / Pope scanning method and contact media.

Note 2: Thyroid, Parathyroid, Breast, Scrotum, Penis in adult, Pediatric and Neonatal Patents

Note 3: The Hudson 900 Ultrasound System is a relabeled Aloka 900 Ultrasound System See K983879

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)

Hudson UST-5524—7.5 40mm Linear Array Ultrasound Transducer

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P						B/M	Note:2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P						B/M	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Wounds		N	N						N- B/M	Note 1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: In conjunction with Wendelken / Pope scanning method and contact media.

Note 2: Thyroid, Parathyroid, Breast, Scrotum, Penis in adult, Pediatric and Neonatal Patents

Note 3: The Hudson UST-5524 probe is a relabeled Aloka UST-5524 probe --See K983879

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lageson

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040926

Prescription Use (Per 21 CFR 801.109)